UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK
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LUCIA BURGOS,

Plaintiff,

v.

MEMORANDUM & ORDER
10-CV-2680 (MKB)

SATIETY, INC.,

Defendant.

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MARGO K. BRODIE, United States District Judge:

Plaintiff Lucia Burgos brought the above-captioned action against Defendant Satiety, Inc., alleging various products liability, statutory violations, and other state law tort claims. Plaintiff's claims are based on injuries sustained by Plaintiff after a transoral gastroplasty procedure where Defendant's Transoral Gastroplasty Stapling System ("TOGA") medical device was used. Plaintiff filed an Amended Complaint which alleges a claim for state law negligence. The parties cross move for summary judgment. Defendant moves for summary judgment on the grounds that Plaintiff does not have standing to bring a private action under the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 *et seq.* ("FDCA") and, even assuming that Plaintiff could bring such an action, Plaintiff has failed to allege sufficient evidence to sustain her claim. Plaintiff moves for summary judgment based on Defendant's destruction and disposal of the TOGA device. The Court finds that Plaintiff has failed to state a claim that the TOGA device was manufactured in violation of the terms, conditions, standards and specifications of the Investigational Device Exemption ("IDE"). The Court denies Plaintiff's motion for summary

judgment and grants Defendant's motion for summary judgment dismissing Plaintiff's Amended Complaint.

I. Background

Plaintiff underwent a transoral gastroplasty procedure on November 19, 2008 at Columbia Presbyterian Hospital, as part of a clinical trial. (Def. 56.1 ¶ 7; Pl. 56.1 ¶ 1.) During the procedure, Defendant's TOGA device was used. (Def. 56.1 ¶¶ 13–14.) The TOGA device was developed pursuant to a plan filed with the Food and Drug Administration ("FDA"), as part of Defendant's IDE. (*Id.* at ¶¶ 16–19.) Prior to the procedure, Plaintiff signed a consent form that listed various risks of the surgery, including a tear within the esophagus. (*Id.* at ¶¶ 11–12.) During the procedure, Plaintiff's esophagus was torn. (*Id.* at ¶ 12.)

After the procedure, the TOGA device was returned to Defendant. (Pl. 56.1 ¶ 3.) The record is not entirely clear regarding when Defendant received the device. (*Id.* at ¶¶ 9–12; 19–20.) However, it is undisputed that at some point the TOGA device was destroyed, though, it is unclear exactly when it was destroyed. (*Id.* at ¶¶ 10, 19–22.) It may have been destroyed in November or December of 2008 or as late as April of 2009. (*Id.*) Under Defendant's Standard Operating Procedure, Defendant retained non-commercial devices for three months and commercial devices for nine months. (*Id.* at ¶¶ 13, 28.)

In a letter to Plaintiff dated April 6, 2009, Defendant offered to "pay [Plaintiff] for 24 weeks (6 months) of lost wages at $1,250 per week, or $30,000 and an additional amount of $28,000 to cover incidental costs during [Plaintiff's] recovery for a total lump sum of **$58,000**. In addition, we have offered to and will pay for gastric bypass surgery or other bariatric procedure if you choose to have it, not to exceed $42,000, to be paid directly to the hospital at the time of the surgery." (Pl. Summ. J. Mot. Ex. F.) (emphasis in original).

By letter dated September 27, 2010, Plaintiff's counsel wrote to Defendant's counsel. (*Id.* at ¶¶ 4–7.) In the letter, Plaintiff asked if the TOGA device used on Plaintiff was in Defendant's possession, and, if Defendant had it, Plaintiff requested that Defendant not tamper with or modify the TOGA device. (*Id.*) If the TOGA device was still in Defendant's possession, Plaintiff asked for an opportunity to inspect and examine it. (*Id.*) On October 12, 2010, Defendant wrote to Plaintiff confirming receipt of Plaintiff's letter and informing Plaintiff that Defendant was not in possession of the TOGA device, as it was disposed of after the procedure. (*Id.* at ¶¶ 7–8.)

II. Procedural History

In November of 2010, United States District Judge John Gleeson dismissed the Plaintiff's first complaint because Plaintiff's state law claims were preempted by federal law. *Burgos v. Saiety*, No. 10-CV-2680, 2010 WL 4907764, at *3 (E.D.N.Y. Nov. 3, 2010) ("*Burgos I*"). However, Judge Gleeson granted Plaintiff leave to file an amended complaint because "parallel" state law claims, which are not "'different from, or in addition to' the requirements imposed by federal law" were not preempted. *Id.* at *3. Plaintiff then filed the Amended Complaint.

On April 5, 2011, Judge Gleeson dismissed two of the three claims in the Amended Complaint. *Burgos v. Satiety*, No. 10-CV-2680, 2011 WL 1327684, at *3 (E.D.N.Y. Apr. 5, 2011) ("*Burgos II*"). The only remaining claim is Plaintiff's negligence claim that the medical device at issue was "manufactured in violation of the terms, conditions, standards and specifications of the [IDE] secured by Satiety." *Id.* IDEs establish strict requirements for the manufacture of devices. *Id.* Companies are supposed to follow their IDEs when manufacturing the devices. *Id.* Judge Gleeson noted that, at the time of his decision, Plaintiff had failed to allege "how the . . . device's manufacture violated the IDE . . . terms, conditions, standards, or

specifications that she claimed were violated." *Id.* However, Judge Gleeson found that such omissions were expected since discovery had not begun and IDEs were confidential. *Id.* He found that Plaintiff was entitled to discovery "in order to determine the terms of Satiety's IDE, and to explore whether or not the specific device used in her procedure was manufactured in accordance with the IDE." *Id.* at *5.

On December 30, 2011, Judge Gleeson compelled discovery to determine whether an adverse inference was warranted due to Defendant's alleged intentional destruction of the device in question. In his order, Judge Gleeson set aside United States Magistrate Judge Roanne Mann's denial of Plaintiff's "motion to compel discovery insofar as it barred discovery on whether [Defendant's] disposal of subject device warrants an adverse inference about the device." *Burgos v. Satiety, Inc.*, No. 10-CV-2680, 2011 WL 6936348, at *2 (E.D.N.Y. Dec. 30, 2011) ("*Burgos III*"). In his opinion, Judge Gleeson found "[t]he destruction of evidence may warrant an adverse inference about the content of that evidence if '(1) relevant evidence is destroyed; (2) with culpability; (3) when the defendant was under a duty to preserve the evidence."' *Id.* (citations omitted). Judge Gleeson found that whether or not an adverse inference was warranted would be important at the summary judgment stage of the case. *Id.* at *3.

III. Discussion

a. Standard of Review

Summary judgment is proper only when, construing the evidence in the light most favorable to the non-movant, "there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a); *see also Redd v. N.Y. Div. of Parole*, 678 F.3d 166, 174 (2d Cir. 2012); *Doninger v. Niehoff*, 642 F.3d 334, 344 (2d Cir. 2011).

The role of the court is not "to weigh the evidence and determine the truth of the matter but to determine whether there is a genuine issue for trial." *Cioffi v. Averill Park Cent. Sch. Dist. Bd. of Educ.*, 444 F.3d 158, 162 (2d Cir. 2006) (quoting *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 249 (1986)). A genuine issue of fact exists when there is sufficient "evidence on which the jury could reasonably find for" the non-moving party. *Anderson*, 477 U.S. at 252. The "mere existence of a scintilla of evidence" is not sufficient to defeat summary judgment; "there must be evidence on which the jury could reasonably find for" the non-moving party. *Id.* The court's function is to decide "whether, after resolving all ambiguities and drawing all inferences in favor of the non-moving party, a rational juror could find in favor of that party." *Pinto v. Allstate Ins. Co.*, 221 F.3d 394, 398 (2d Cir. 2000).

b. Plaintiff Has Standing

Defendant argues that Plaintiff's negligence claim alleges a violation of the FDCA. (Def Summ. J. 7–10.) Defendant further argues that only the United States can bring an action under the FDCA, and, therefore, Plaintiff has no standing to bring this action. (*Id*.) In support of its motion for summary judgment on the basis of standing, Defendant relies on a number of cases where courts have found that there is no private right of action to enforce the FDCA. *See PDK Labs, Inc. v. Friedlander*, 103 F.3d 1105, 1113 (2d Cir. 1997) ("no . . . private right of action exists" to enforce the FDCA); *Gile v. Optical Radiation Corp*., 22 F.3d 540, 544 (3d Cir. 1994) ("[V]iolations of the FDCA do not create private rights of action."); *Lewkut v. Stryker Corp.*, 724 F. Supp. 2d 648, 659 (S.D. Tex. 2010) ("[T]he statutory language of the FDCA, as well as case law, makes clear that the provisions of the FDCA, including that which establishes and defines the prohibition on 'adulterated devices[,]' are to be enforced through the United States government only." (citation omitted) (collecting cases)); *Murphy v. Cuomo*, 913 F. Supp. 671,

679 (N.D.N.Y. 1996) (granting summary judgment on claims based on the FDCA because the statute does not contain a private right of action); *Brinkman v. Shiley, Inc.*, 732 F. Supp. 33, 35 (M.D. Pa. 1989), *aff'd*, 902 F.2d 1558 (3d Cir. 1989) ("The FDCA does not create or imply a private right of action for individuals injured as a result of violations of the Act.").

However, contrary to Defendant's argument, Plaintiff is not bringing an action under the FDCA, but rather, a state negligence action. As Judge Gleeson explained, "the federal regulatory scheme 'does not prevent a State from providing a damages remedy for claims premised on a violation of FDA regulation.'" *Burgos II*, 2011 WL 1327684, at *1 (citations omitted); *see also Riegel v. Medtronic, Inc.*, 552 U.S. 312, 330 (2008) (holding that states may provide "damages remedy for claims premised on a violation of FDA regulations," where they are "'parallel,' rather than add to, federal requirements"); *Stengel v. Medtronic Inc.*, 704 F.3d 1224, 1233 (9th Cir. 2013) (holding that a plaintiff may bring a state law negligence claim "insofar as the state-law duty parallels a federal-law duty under" the Medical Device Amendments ("MDA") to FDCA); *Bass v. Stryker Corp.*, 669 F.3d 501, 509 (5th Cir. 2012) (holding that plaintiffs may plead parallel state common law claims based "on a violation of FDA regulation" and "a formal finding of a violation by the FDA was not required to plead a parallel action"); *Walker v. Medtronic, Inc.*, 670 F.3d 569, 577 (4th Cir. 2012), *cert. denied*, 133 S. Ct. 162 (2012) (noting that private litigants may bring state law claims "when state duties . . . parallel, rather than add to, federal requirements. This situation occurs when claims are premised on a violation of FDA regulations." (alteration in original) (citations and internal quotation marks omitted)); *Wolicki-Gables v. Arrow Int'l., Inc.*, 634 F.3d 1296, 1301 (11th Cir. 2011) (holding that plaintiffs may bring "a parallel claim" to FDA regulations); *Bausch v. Stryker Corp.*, 630 F.3d 546, 553–58 (7th Cir. 2010) (holding that plaintiffs may bring parallel state law claims to the FDCA); *In re*

Medtronic, 623 F.3d 1200, 1205–07 (8th Cir. 2010) (discussing various parallel claims); *Gelber v. Stryker Corp.*, 788 F. Supp. 2d 145, 156 (S.D.N.Y. 2011) ("The regulations state, '[g]enerally, section 521(a) does not preempt a State or local requirement prohibiting the manufacture of adulterated or misbranded devices.'" (citations omitted)). Judge Gleeson found that Plaintiff had stated a "state law negligence claim predicated upon [Defendant's] failure to manufacture the TOGA device used in [Plaintiff's] surgery . . . in conformity with the IDE." *Burgos III*, 2011 WL 6936348, at *2. Defendant's claim that Plaintiff cannot maintain her negligence claim is without merit and Defendant's summary judgment motion based on lack of standing is denied.

c. Plaintiff Has Failed to State a Claim

Defendant next argues that, even assuming Plaintiff has standing to bring an action, Plaintiff has not presented sufficient evidence to sustain her claim because she has failed to sufficiently plead how the TOGA device used on Plaintiff deviated from the IDE. (Def. Summ. J. 10–13.) Plaintiff argues that she cannot say how the manufacture of the TOGA device violated the IDE, since the device has been destroyed. (Pl. Summ. J. 9–11; Pl. Opp'n 6–9.) Plaintiff has failed to even plead a theory of how the IDE was violated and how this violation led to Plaintiff's injury. Plaintiff has, therefore, failed to meet her burden to state a valid claim. *See, e.g.*, *Bass*, 669 F.3d at 511–12 (holding that in order to adequately plead a parallel claim, a plaintiff must plead "the existence of a manufacturing defect caused by a violation of federal regulations and allegations connecting a defect in the manufacture of the specific device to that plaintiff's specific injury").

Courts have dismissed similar parallel claims where plaintiffs have failed to plead with specificity how the federal regulation was violated. *See, e.g.*, *Wolicki-Gables*, 634 F.3d at 1301 (upholding the district court's dismissal because the complaint failed to "provide any

factual detail to substantiate that crucial allegation"); *In re Medtronic*, 623 F.3d at 1205–07 ("Plaintiffs simply failed to adequately plead that Medtronic violated a federal requirement specific to the FDA's . . . approval[.]"); *Gale v. Smith & Nephew, Inc.*, No. 12-CV-3614, 2013 WL 563403, at *4 (S.D.N.Y. Feb. 13, 2013) (dismissing the complaint where "plaintiff neither provide[d] a factual basis for finding [the defendant] violated federal law, nor allege[d] facts supporting an inference that he was implanted with products designed or manufactured in contravention of the FDA's premarket approval"); *Ilarraza v. Medtronic, Inc.*, 677 F. Supp. 2d 582, 589 (E.D.N.Y. 2009) (dismissing a complaint because the "[p]laintiff fail[ed] to set forth any specific problem, or failure to comply with any FDA regulation that can be linked to the injury alleged").

Judges, including Judge Gleeson in this case, have reasoned that plaintiffs should be given leeway prior to discovery with regard to pleading specifics concerning exactly how a device was altered and what regulations were violated. *Burgos II*, 2011 WL 1327684 at *4 (allowing Plaintiff to seek additional discovery "because the information she requires to provide the requisite degree of specificity — the IDE documentation submitted by [Defendant] to the FDA — is confidential and not available to the public"); *see also Bausch*, 630 F.3d at 558 ("[Since] much of the product-specific information about manufacturing needed to investigate such a claim fully is kept confidential by federal law[,][f]ormal discovery is necessary before a plaintiff can fairly be expected to provide a detailed statement of the specific bases for her claim."); *Medtronic*, 623 F.3d at 1211 (Melloy, J., concurring in part and dissenting in part) (stating that the plaintiff should have been granted discovery to adduce sufficient facts to allege how the manufacture of the device violated "FDA-approved specifications").

Judge Gleeson granted Plaintiff leave for a "limited amount of discovery that would permit her to make a factually-based claim that Satiety's manufacturing process did not comport with its IDE." *Burgos II*, 2011 WL 1327684, at *4. As part of discovery, Plaintiff obtained the manufacturing records regarding the TOGA device. (Def. Opp'n 15.) Plaintiff also took the deposition of Allan Abati, Ph.D., Defendant's former Vice President of Regulatory Affairs, Quality Assurance and Clinical Programs, who communicated with the FDA regarding Defendant's IDE for the TOGA device, and two depositions of Robert Gaffney, Defendant's former Vice President of Operations, who was responsible for ensuring that the TOGA device was manufactured in accordance with the IDE. (Pl. 56.1 ¶¶ 15, 17, Def. Summ. J. 9–13.) Despite this discovery, Plaintiff has failed to allege any additional facts relating to the manufacture of the device in support of her claim. This failure is fatal to Plaintiff's claim. As discussed below, Plaintiff's reliance on the theory of adverse inference is insufficient to overcome the deficiency in Plaintiff's pleading.

d. Plaintiff Cannot Benefit From an Adverse Inference

Plaintiff relies on the theory of adverse inference to argue that because Defendant destroyed the device, Defendant's motion for summary judgment should be denied and Plaintiff's motion for summary judgment should be granted.[1] (Pl. Summ. J. 9–11; Pl. Opp'n 6–

[1] Plaintiff relies on Judge Gleeson prior orders as the basis for why she is entitled to an adverse inference. (Pl. Summ. J. 2–5, 9.) As an initial matter, Plaintiff's reliance on Judge Gleeson's orders is misplaced. None of Judge Gleeson's orders said that Plaintiff was entitled to an adverse inference. Indeed, both his April 5, 2011 and December 30, 2011 opinions state that the disposal of the TOGA device *might* warrant an adverse inference. *See Burgos II*, 2011 WL 1327684 at *3 & n.7 (noting Defendant's failure to keep the device "*may* . . . perhaps even warrant some form of relief at trial" like an adverse inference (emphasis added)), *Burgos III*, 2011 WL 6936348, at *2 ("[Defendant's] disposal of the device *could* support an adverse inference regarding what an inspection of the device would have revealed about how it was manufactured." (emphasis added)).

9.) Adverse inferences are appropriate where "'(1) relevant evidence is destroyed; (2) with culpability; (3) when the defendant was under a duty to preserve the evidence.'" *Burgos III*, 2011 WL 6936348, at *2 (citations omitted); *see also Residential Funding Corp. v. DeGeorge Fin. Corp.*, 306 F.3d 99, 107–08 (2d Cir. 2002) (discussing the requirements for adverse inferences); *Curcio v. Roosevelt Union Free Sch. Dist.*, 283 F.R.D. 102, 108 (E.D.N.Y. 2012) (same); *Valenti v. Penn Mut. Life Ins. Co.*, 850 F. Supp. 2d 445, 452 (S.D.N.Y. 2012), *aff'd*, 2013 WL 440224 (2d Cir. Feb. 6, 2013) (same). Granting a dispositive motion based on an adverse inference is an extreme remedy and should be used sparingly. *See Dahoda v. John Deere Co.*, 216 F. App'x 124, 125 (2d Cir. 2007); *West v. Goodyear Tire & Rubber Co.*, 167 F.3d 776, 779 (2d Cir. 1999); *Arista Records LLC v. Usenet.com, Inc.*, 608 F. Supp. 2d 409, 442 (S.D.N.Y. 2009). It can be appropriate when bad faith and willfulness is demonstrated and there is no other remedy available.[2] *See Dahoda*, 216 F. App'x at 125 (holding that dismissal as a sanction for spoliation of evidence was not appropriate because "[p]laintiffs' conduct here is not so egregious as to warrant the harshest sanction of summary dismissal"); *West*, 167 F.3d at 779 ("Dismissal is appropriate if there is a showing of willfulness, bad faith, or fault on the part of the sanctioned party. However, because dismissal is a 'drastic remedy,' it 'should be imposed only in extreme circumstances, usually after consideration of alternative, less drastic sanctions.'" (citations omitted)); *Arista Records LLC*, 608 F. Supp. 2d at 442 ("The degree of culpability

[2] Even giving an adverse inference instruction to the jury is considered an extreme sanction. *Williams v. N.Y.C. Transit Auth.*, No. 10-CV-0882, 2011 WL 5024280, at *11 (E.D.N.Y. Oct. 19, 2011) ("An 'adverse inference instruction is an extreme sanction and should not be given lightly,' . . . 'An adverse inference instruction . . . can give the impression that the court thinks the jury ought to draw the inference. The suggestive force of the adverse inference instruction is precisely the reason for the court's careful analysis before ordering it.'" (citations omitted)); *R.F.M.A.S., Inc. v. So*, 271 F.R.D. 13, 52 (S.D.N.Y. 2010) ("An adverse inference instruction is a severe sanction.").

bears on the severity of sanctions that are warranted. Severe sanctions for discovery violations, including dismissal, may be imposed for intentional conduct, such as bad faith or gross negligence." (quoting *Reino De Espana v. Am. Bureau of Shipping*, No. 03-CV-3573, 2007 WL 1686327, at *3 (S.D.N.Y. June 6, 2007)). A plaintiff can survive summary judgment with an adverse inference, if the plaintiff has met the spoliation test and provided "some (not insubstantial) evidence" in his or her favor. *Byrnie v. Town of Cromwell, Bd. of Educ.*, 243 F.3d 93, 107 (2d Cir. 2001) (quoting *Kronisch v. United States*, 150 F.3d 112, 128 (2d Cir. 1998)). Plaintiff has failed to (1) establish bad faith and willfulness on the Defendant's part or (2) provide any evidence in support of her case. Therefore, Plaintiff's motion for summary judgment is denied, and Defendant's motion for summary judgment is granted.

i. Plaintiff has not shown bad faith or willfulness

In his December 10, 2011 decision, Judge Gleeson stated that the factors that would be relevant in determining whether an adverse inference is appropriate include "why Satiety destroyed the subject device; whether Satiety's disposal of the device violated any applicable administrative regulations or statutes; whether Satiety knew or should have known that the device would be relevant to future litigation; whether Satiety destroyed the device knowingly, even without intent to breach a duty to preserve it, or negligently; and any other evidence tending to show that an inspection of the device would have exposed that it was not manufactured in accordance with the IDE." *Burgos III*, 2011 WL 6936348, at *2 (citations omitted); *see also Byrnie*, 243 F.3d at 107–08 (stating that "a case by case approach was appropriate" for determining whether an adverse inference applies and courts should consider the destroying party's state of mind, whether the destroying party had a duty to preserve either because of litigation or legal obligation, and whether the evidence would have been relevant to non-

destroying party's case). Plaintiff addresses only one of these factors. Plaintiff alleges that the letter offering to pay Plaintiff money was a sign that Defendant knew the device would be relevant to future litigation. (Pl. Summ. J. 9–11.)

Plaintiff argues that summary judgment in her favor is warranted because Defendant should have known litigation was imminent since the TOGA device failed during Plaintiff's surgery, Defendant took possession of the TOGA device, and Defendant offered to pay Plaintiff's medical bills and lost wages in April 2009. (Pl. Summ. J. 9–11.) However, these facts alone fail to demonstrate willfulness or bad faith on Defendant's part. First, it is undisputed that Defendant had a policy of destroying devices within three months for non-commercial devices, which it appears the TOGA device was, and nine months for commercial devices. (Pl. 56.1 ¶¶ 14, 28; Def's Opp'n Ex. A.) If this policy was not followed to the letter, as Plaintiff alleges, i.e., if the device had been destroyed prior to the three months, Plaintiff has provided no evidence that this early destruction was done willfully rather than negligently. (*See* Pl. 56.1 ¶¶ 14, 28; Def. 56.1 ¶ 9.) Second, Plaintiff signed a consent form that listed as a potential danger of the surgery a torn esophagus, which is what occurred. (Def. 56.1 ¶¶ 13–14.) Having suffered an injury that Plaintiff knew and understood was a possibility, without more evidence, there is no indication that Defendant should have known that Plaintiff would sue, especially where Defendant was not sued until a year and a half after the surgery. Plaintiff did not file a complaint until June 2010 and did not request the TOGA device until September 2010, well over a year after it was Defendant's policy to destroy the device. Under these circumstances, Defendant's actions were not so egregious to warrant summary judgment in Plaintiff's favor.[3] *See, e.g.*,

[3] Plaintiff asserts that there is some evidence that the device had been destroyed prior to the three-month period outlined in Defendant's Standard Operating Procedure. (Pl. 56.1 ¶ 10.) However, other than suggesting that Plaintiff was offered a settlement in April 2009, Plaintiff has

Fujitsu Ltd. v. Fed. Exp. Corp., 247 F.3d 423, 436 (2d Cir. 2001) (holding adverse inference was not warranted where the defendant waited to ask the plaintiff for the destroyed evidence long after the incident occurred and not until motion practice).

ii. Plaintiff has not provided any evidence that the TOGA device was manufactured in violation of the IDE

Even assuming that this Court were to find that Plaintiff is entitled to an adverse inference because Plaintiff somehow met the elements of the spoliation test, Plaintiff would still be under an obligation to produce some evidence that the TOGA device had been manufactured in a way that violated the IDE in order to survive summary judgment. Plaintiff has not produced any such evidence. "In borderline cases, an inference of spoliation, in combination with 'some (not insubstantial) evidence' for the plaintiff's cause of action, can allow the plaintiff to survive summary judgment." *Byrnie*, 243 F.3d at 107 (quoting *Kronisch*, 150 F.3d at 128). In *Kronisch*, the Second Circuit found that "plaintiff's circumstantial evidence" combined with the fact the "jury should be permitted (but not required) to draw an adverse inference" given Defendant's

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provided no evidence that the device was destroyed willfully. Even assuming Plaintiff could show that the device was destroyed negligently prior to the three-month period under Defendant's Standard Operating Procedure, the appropriate remedy would be an adverse inference charge at trial, not summary judgment in favor of Plaintiff. *See Arista Records LLC v. Usenet.com, Inc.*, 608 F. Supp. 2d 409, 434 (S.D.N.Y. 2009) ("'The degree of culpability bears on the severity of sanctions that are warranted. Severe sanctions for discovery violations, including dismissal, may be imposed for intentional conduct, such as bad faith or gross negligence.' Lesser sanctions, such as an adverse inference instruction, may be imposed where a party acted 'knowingly, even if without intent . . . or negligently.'" (citations omitted)); *see also Dahoda v. John Deere Co.*, 216 F. App'x 124, 125 (2d Cir. 2007) (denying motion for dismissal based on spoliation of evidence, where there were appropriate lesser sanctions); *West v. Goodyear Tire & Rubber Co.*, 167 F.3d 776, 779 (2d Cir. 1999) (same); *Kronisch v. United States*, 150 F.3d 112, 128 (2d Cir. 1998) (finding that the appropriate remedy for the defendant's destruction of evidence was an adverse inference at trial). An adverse inference is warranted for negligent destruction of evidence when the defendant was under a duty to preserve the evidence, the defendant negligently allowed the evidence to be destroyed, and the evidence was relevant. *Residential Funding Corp.*, 306 F.3d at 108; *Curcio v. Roosevelt Union Free Sch. Dist.*, 283 F.R.D. 102, 111 (E.D.N.Y. 2012).

spoliation of evidence was sufficient for the plaintiff's claim to survive summary judgment. 150 F.3d at 126. In *Kronisch*, the plaintiff alleged that he had been drugged by a particular CIA agent in Paris in 1952. *Id.* at 128–30. The files for the alleged CIA program had been destroyed. *Id.* The Second Circuit found that the plaintiff's case could proceed to trial based on various circumstantial facts including: plaintiff's statement that a club-foot person drugged him – the alleged agent had a club foot; "that very few Americans – other than those working with the CIA – knew of or had access to LSD in 1952; that [the defendant] was engaged in some form of LSD research in 1952; that the CIA performed LSD tests on unwitting subjects in the United States at or near the relevant time; that the CIA drug tests were at times performed using the same means alleged here; [and] that the CIA tested LSD abroad." *Id.*

Plaintiff has failed to provide any circumstantial evidence, other than the fact that Plaintiff was injured and that she was offered some money, to argue that the TOGA device was actually manufactured in a way that violated the IDE.[4] *Kronisch*, 150 F.3d at 128 ("We do not

[4] Plaintiff was injured in a manner that was explicitly accounted for in the consent form that Plaintiff signed prior to her surgery. (*Id.* at ¶¶ 11–12) To sustain a claim, Plaintiff needs to marshal some evidence other than the injury to demonstrate that the TOGA device had been manufactured in violation of the IDE or, at a minimum, develop a clear theory of how the TOGA device was manufactured in violation of the IDE. *See Walker v. Medtronic, Inc.*, 670 F.3d 569, 578–80 (4th Cir. 2012), *cert. denied*, 133 S. Ct. 162 (2012) (upholding district courts grant of summary judgment where the plaintiff could not point to any facts supporting a finding that the device was "designed, manufactured, and distributed [not] in compliance with the terms of the FDA's premarket approval"); *Gale v. Smith & Nephew, Inc.*, No. 12-CV-3614, 2013 WL 563403, at *4 (S.D.N.Y. Feb. 13, 2013) (dismissing the complaint where "plaintiff neither provide[d] a factual basis for finding [the defendant] violated federal law, nor allege[d] facts supporting an inference that he was implanted with products designed or manufactured in contravention of the FDA's premarket approval"); *Gelber v. Stryker Corp.*, 752 F. Supp. 2d 328, 335 (S.D.N.Y. 2010) (dismissing the plaintiffs claim where they had "not pointed to evidence of device-specific violations of federal law or alleged how those violations have a cognizable link to the [plaintiff's] injuries"); *Ilarraza v. Medtronic, Inc.*, 677 F. Supp. 2d 582, 589 (E.D.N.Y. 2009) (holding that a plaintiff who does not plead a specific violation of an FDA regulation cannot sustain a claim).

suggest that the destruction of evidence, standing alone, is enough to allow a party who has produced no evidence – or utterly inadequate evidence – in support of a given claim to survive summary judgment on that claim."). Plaintiff has not presented any evidence that the TOGA device was "adulterated," or that it was "unreasonably dangerous and unfit for [its] intended purpose" to show that the IDE was violated. *See, e.g.*, *Gelber v. Stryker Corp.*, 752 F. Supp. 2d 328, 335 (S.D.N.Y. 2010) (dismissing the plaintiffs' claim where they had "not pointed to evidence of device-specific violations of federal law or alleged how those violations have a cognizable link to the [plaintiff's] injuries"). Failure to provide *any* evidence in support of Plaintiff's claim is fatal and it must be dismissed. *See Tucker v. New York City*, 376 F. App'x 100, 103 (2d Cir. 2010) (upholding denial of plaintiff's summary judgment motion and denial of plaintiff's request for an adverse inference where the plaintiff had failed to produce any evidence to support her claim); *Blasi v. N.Y.C. Bd. of Educ.*, No. 00-CV-5320, 2012 WL 3307346, at *6 & n.4 (E.D.N.Y. Aug. 12, 2012) (granting summary judgment because even if the court had given the plaintiff an adverse inference, plaintiff did not have sufficient circumstantial evidence to support her claim and thus survive summary judgment); *Kravtsov v. Town of Greenburgh*, No. 10-CV-3142 CS, 2012 WL 2719663, at *8 & n.20 (S.D.N.Y. July 9, 2012) (noting that since "[n]one of [the] [p]laintiffs claims dismissed below are of the borderline variety[,] . . . the adverse inference does not save otherwise meritless claims from summary judgment in [the] [d]efendants' favor"). That Court finds that Plaintiff has failed to establish that she is entitled to summary judgment and her motion is denied. Plaintiff has also failed to state a claim, and, therefore, Defendant's summary judgment is granted.[5]

[5] The Court recognizes its authority to *sua sponte* grant leave to Plaintiff to amend the Amended Complaint. *Steger v. Delta Airlines, Inc.*, 382 F. Supp. 2d 382, 387 (E.D.N.Y. 2005) ("Rule 15(a) of the Federal Rules of Civil Procedure states that leave to amend a pleading 'shall

IV. Conclusion

For the foregoing reasons, the Court denies Plaintiff's motion for summary judgment and grants Defendant's motion for summary judgment dismissing Plaintiff's Amended Complaint on the ground that Plaintiff has failed to state a claim that the TOGA device was manufactured in violation of the terms, conditions, standards and specifications of the IDE. The Clerk of the Court is directed to close the case.

SO ORDERED:

s/MKB
MARGO K. BRODIE
United States District Judge

Dated: March 5, 2013
Brooklyn, New York

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be freely given when justice so requires.' In that regard, even if not requested by the [p]laintiff, the Court may *sua sponte* grant leave to amend." (citations omitted)); *Straker v. Metro. Transit Auth.*, 333 F. Supp. 2d 91, 102–03 (E.D.N.Y. 2004) ("[T]he Court may *sua sponte* grant leave to amend. The Court's discretion is 'broad[,]' and 'its exercise depends upon many factors, including undue delay, bad faith or dilatory motive on the part of the movant, repeated failure to cure deficiencies by amendments previously allowed, undue prejudice to the opposing party by virtue of allowance of the amendment, futility of amendment, etc.'" (citations omitted)). Here, an amendment would be futile. Plaintiff deposed several of Defendant's employees and obtained the manufacturing records for the TOGA device. (*See* Def. Opp'n 15; Def. Summ. J. 10–13.) However, Plaintiff was not able to locate any evidence in support of her claim that the TOGA device was not manufactured in accordance with the IDE. *See*, *e.g.*, *Bass v. Stryker Corp.*, 669 F.3d 501, 511–12 (5th Cir. 2012) (holding that in order to adequately plead a parallel claim, a plaintiff must plead "the existence of a manufacturing defect caused by a violation of federal regulations and allegations connecting a defect in the manufacture of the specific device to that plaintiff's specific injury"); *Ilarraza*, 677 F. Supp. 2d at 589 (dismissing a complaint because the plaintiff could provide no facts "to set forth any specific problem, or failure to comply with any FDA regulation that can be linked to the injury alleged ").